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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,193	03/25/2002	Jean-Pierre Molitor	H 4157 PCT/US	1128
23657	7590	08/25/2005	EXAMINER	
COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

MC

Office Action Summary

Application No.

09/980,193

Applicant(s)

MOLITOR ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/23/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) 23-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/23/05 has been entered.

Claims 12-22 are being considered on the merits.

Claims 23-35 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for mixtures comprising “a carbon source or a transformant”. Nothing in the instant as-filed specification is directed to the use of transformed microorganisms or “transformants”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite in the recitation of “mixtures comprising a carbon source or a transformant”. There is no clear indication as to the nature or source of the “transformant” in this context. See also the new matter rejection *supra*.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-22 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Inlow *et al.* taken with Kopp-Holtwiesche (DE 3738812) and Forster *et al.* (WO 95/11660) for the reasons as stated in the last Office action and the further reasons below.

Inlow *et al.* discloses a reaction medium comprising a microemulsion and the microorganisms insect cells wherein the size distribution overlaps and which contains the same ingredients (see, e.g., Example 8, Example 9 and Example 2). The reference differs from the claimed invention a fatty acid methyl ester is not used in the medium. However, Kopp-Holtwiesche discloses a similar microbial reaction medium containing methyl laurate or other fatty acid methyl esters (See, e.g., Examples 1 and 3).

The references differ from the claimed invention in that at least Inlow *et al.* use an animal oil rather than a vegetable oil. However, Forster *et al.* adequately demonstrate that it is routine in this art to use a variety of triglycerides for the production of various emulsions (See, e.g. page 5, last paragraph). The Forster *et al.* reference also discloses the use of two emulsifiers in combination wherein one acts as a coemulsifier (See, e.g., page 8) and various amounts and combinations of these emulsifiers. The emulsions are produced by the "phase inversion temperature" (PIT) method.

While the compositions of Forster are not explicitly disclosed as being reaction media containing microorganisms, it is well recognized in the art that cosmetic compositions such as those disclosed in the reference are not sterile upon opening and are highly susceptible to

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microbial degradation. Thus they clearly constitute “a reaction medium” and can reasonably be presumed to contain microorganisms as claimed.

The ranges of ingredient content discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of the amounts used in the reaction medium preparation for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

It is also noted that the composition is claimed as containing a “phase inversion temperature emulsion”, which constitutes claiming as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness or anticipation for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the reaction medium of Inlow *et al.* by substituting microemulsions containing animal oils with microemulsions containing fatty acid alkyl esters, and methyl esters in particular, as suggested by the teachings of Kopp-Holtwiesche and/or a variety of oils including specific vegetable oils as taught by Forster *et al.* (WO 95/11660), as well as altering the proportions of the various ingredients for optimization purposes for the expected economic benefit of enhancing the bioavailability of the lipids to recalcitrant microbial that will support their growth and proliferation as well as providing the option of not having the filter sterilize the lipid fraction and the rest of the media components separately. The growth and proliferation of recalcitrant microorganism has the expected benefit of increasing the yields of pharmaceutically and industrially important metabolites and/or aiding in the identification of pathogenic microorganisms.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

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Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Inlow would not suggest that the microemulsion of the fatty material could be utilized as a carbon source in a culture medium. The basis for this argument is not understood, since the claims as amended specifically comprise a carbon source. Moreover, microorganisms will utilize as a carbon source any material present in a culture medium, whether it is explicitly recited for that purpose or not. The specific details and/or purposes of the processes of Inlow *et al.* and Kopp-Holtwiesche are not relevant to the particulars of the culture medium compositions disclosed. Regarding the amounts of microemulsion now argued, it is noted with all due respect that the claims as written and presented for examination are devoid of any limitations regarding the amount of microemulsion contained therein. Therefore this line of argument fails to persuade.

Forster *et al.* is cited to adequately demonstrate that the use of PIT method in the preparation of a composition comprising an emulsion is old and well known in the art. One of ordinary skill in the art would reasonably have expected the cosmetic composition of Forster *et al.* to contain microorganisms at least to some extent upon expose to air, and applicants have not demonstrated otherwise. In response to applicant's argument that Forster fails to meet the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The medium disclosed in Forster would be suitable for the culturing of a fatty acid degrading strain such as the *C. tropicalis* strain disclosed by Kopp-Holtwiesche that degrades at least fatty acid components of triglycerides (See, e.g., Example 3).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re* Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, all of the references pertain to the addition of triglycerides or fatty acid alkyl esters to media suitable for culturing microorganisms or for sustaining their growth. It is noted in this regard that at least

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Inlow *et al.* and Kopp-Holtwiesche are directed to culture media comprising microorganisms.

Note still further that, contrary to applicant's argument, it is well established that motivation for combining references need not come from the references themselves, as long as applicant's disclosure is not improperly used in a hindsight reconstruction of the claimed invention. *See Ex parte Levengood*, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.") (Citations omitted.)

With respect to applicant's arguments that one of ordinary skill in the art would not have modified the culture medium of Inlow according to the teachings of Kopp-Holtwiesche because lauric acid methyl esters are not part of an emulsion used in the reaction medium. Inasmuch as the amount of emulsion contained in the present culture medium is not disclosed, it is uncertain that all of the medium is emulsified. It is noted that the composition of Kopp-Holtwiesche would have been reasonably expected by one of ordinary skill in the art to be naturally emulsified at least to some extent as a consequence of agitation (See, e.g., Examples). In addition a reaction medium is no more than a composition that supports the growth of a microorganism.

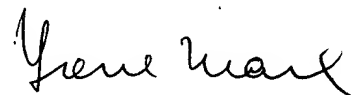
Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



IRENE MARX
PRIMARY EXAMINER